

NATURE OF CHARGE: On or about March 24 and April 9, 11, 14, and 15, 1953, while a number of *thyroid tablets*, *Seconal Sodium capsules*, *capsules containing a mixture of Seconal Sodium and Amytal Sodium*, and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were being held for sale at Center Drug Store of Durham, Inc., after shipment in interstate commerce, various quantities of the *Seconal Sodium capsules* and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were dispensed upon requests for refills of written prescriptions for such drugs without obtaining authorization from the prescriber; and various quantities of the other drugs involved were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale. The corporation and Defendant Ridenhour were charged with causing the acts of dispensing involved in all counts of the information; Defendant Lea was included as a defendant with respect to the dispensing on April 14 of *capsules containing a mixture of Seconal Sodium and Amytal Sodium* and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil*; and Defendant Burwell was joined as a defendant with respect to the dispensing on April 9 of the *thyroid tablets*.

DISPOSITION: September 28, 1953. The defendants having entered pleas of guilty, the court fined the corporation \$500, Defendant Ridenhour \$500, Defendant Lea \$250, and Defendant Burwell \$250. The court also placed the corporation and Defendant Ridenhour on probation for 2 years.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4263. Misbranding of laxative herb tablets. U. S. v. 2 Drums, etc. (F. D. C. No. 35412. Sample No. 37516-L.)

LABEL FILED: September 9, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about May 5, 8, and 20, 1953, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 2 drums, each containing 22,500 tablets, and 9 drums, each containing 43,000 tablets, of *laxative herb tablets* at Newark, N. J., in possession of Miller Co., Inc., together with a number of leaflets entitled "This is the result of becoming thoroughly acquainted with J. Miller's Laxative Herb Compound #6."

RESULTS OF INVESTIGATION: The tablets contained in the drums were to be repackaged by the consignee into 250-tablet size packages. The leaflets were printed locally for the consignee.

LABEL, IN PART: (Drum) "Product Laxative Herb Tab."; (package) "J. Miller's Laxative Herb Compound No. 6 Pure Herbs 250 Tablets Active Ingredients: Senna and Frangula Inactive Ingredients: Triticum, Fennel, Gentian and Agar."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for sour stomach, gallbladder, liver, kidney, and urinary bladder trouble, rheumatic pains, arthritis, diabetes, and many other common ailments. The article was not an adequate and effective treatment for such

conditions. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to bear adequate directions for use as a laxative and failed to warn against the use of the article when symptoms of appendicitis were present; and, Section 503 (b) (4), the labeling of the article bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to the provisions of Section 503 (b) (1). The article was misbranded in the above respects when introduced into and while in interstate commerce.

DISPOSITION: October 15, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4264. Misbranding of phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Ken Reynolds Pharmacies, Inc., Kenneth R. Reynolds, and Walter J. Foohey. Pleas of nolo contendere. Fine of \$300 against corporation and \$250 against Kenneth R. Reynolds, plus costs. Sentence suspended against Walter J. Foohey. (F. D. C. No. 33718. Sample Nos. 31208-L, 31209-L, 31211-L, 31329-L, 32503-L, 32504-L.)

INFORMATION FILED: October 4, 1952, Western District of Missouri, against Ken Reynolds Pharmacies, Inc., Joplin, Mo., Kenneth R. Reynolds, president, and Walter J. Foohey, a pharmacist for the corporation.

ALLEGED VIOLATION: On or about July 31, October 1 and 31, and November 2, 1951, while a number of *phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital* were being held for sale at Ken Reynolds Pharmacies, Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. The corporation was charged with causing the acts of repacking and dispensing involved in each of the 6 counts of the information; Kenneth R. Reynolds was joined as a defendant in 5 of the counts; and Walter J. Foohey was joined as a defendant in 1 count.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

*See also No. 4263; veterinary preparations, Nos. 4279, 4280.